New Approvals

ANADA Number: 200-256

Pioneer Product:	134-708
Trade Name:	Iron Dextran Injection-200
Ingredients:	Iron dextran complex
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	08/17/98
Status:	Over-the-counter
Route:	Intramuscular
Species:	Porcine (baby pigs)
Drug Form:	Liquid (solution)
Concentration:	200 mg/mL of elemental iron as iron dextran complex
Indications:	For prevention or treatment of anemia due to iron deficiency
Tolerance:	Not established
Withdrawal:	Not established

21CFR 522.1182

NADA Number: 140-947

Trade Name:	Maxiban®, Lincomix®
Ingredients:	Narasin, nicarbazin, lincomycin
Sponsor:	Elanco Animal Health
Approval Date:	09/03/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (broiler chickens)
Drug Form:	Type A medicated articles to make combination drug Type C medicated feeds
Concentration:	Narasin and nicarbazin: 36 grams of activity per pound each in the Type A medicated article Lincomycin: 4. 10, 20, or 50 grams of activity per pound of Type A medicated article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E .acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.428 Narasin: A tolerance for residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm muscle; 1.8 ppm in liver; 1.2 ppm in skin with adhering fat. 21CFR 556.445 Nicarbazin: A tolerance of 4 ppm is established for residues in uncooked chicken muscle, liver, skin, and kidney. 21CFR 556.360 Licomycin: A tolerance for residues in chickens is not required.
Withdrawal:	5 days

21CFR 558.325, *558.363*, and *558.366*

NOTE: This original NADA provides for the combined use of two approved Type A medicated articles; narasin/ nicarbazin in a 1:1 fixed ratio, and lincomycin in the manufacture of Type C medicated feeds, rather than a premix incorporating both of these compounds, and requires a licensed feed mill.

Supplemental Approvals

NADA Number: 141-035

Trade Name:	Program® Flavor Tabs™
Ingredients:	Lufenuron
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	08/01/98
Status:	Over-the-counter
Route:	Oral
Species:	Canine, feline
Drug Form:	Tablet
Concentration:	45, 90, 204.9, and 409.8 mg
Indications:	Canine: For the prevention and control of flea populations in dogs and puppies six weeks of age and older. Feline: For the control of flea populations in cats and kittens six weeks of age or older.
Patent Number:	5,416,102 Expiration Date 05/2012 5,420,163 05/2012 4,798,837 01/2006

This supplemental provides for adding a flavored tablet formulation with the same indications as the non-flavored tablets.

21CFR 520.1288

NADA Number: 140-937

Trade Name:	Coban®, BMD®
Ingredients:	Monensin sodium, bacitracin methylene disalicylate
Sponsor:	Elanco Animal Health
Approval Date:	08/13/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (growing turkeys)
Drug Form:	Type A medicated article to make Type C medicated feed
Concentration:	Monensin sodium 45 and 60 g/lb; bacitracin methylene disalicylate 25, 30, 40, 50, 60, and 75 g/lb.
Indications:	For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis* and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.
Tolerance:	21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of turkeys. 21CFR 556.420: Monensin: A tolerance for marker residues in turkeys is not needed.
Withdrawal:	Zero days

This supplemental application provides for a new combination including bacitracin methylene disalicylate, as an aid in the control of transmissible enteritis complicated by susceptible organisms at a new use level, when used in Type C medicated feeds in combination with monensin for the prevention of coccidiosis.

21CFR 558.355

NADA Number: 141-011

Trade Name:	Denagard® 10, Chlortetracycline Type A Medicated Articles
Ingredients:	Tiamulin hydrogen fumarate, chlortetracycline hydrochloride
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	08/06/98
Drug Form:	Type A medicated article to make Type B or C medicated feed

This supplemental application provides for an additional manufacturer of Chlortetracycline Type A Medicated Article for combination use with Tiamulin in swine feed.

21CFR 558.600

NADA Number: 140-890 (two approvals)

Trade Name:	Excenel® Sterile Suspension
Ingredients:	Ceftiofur hydrochloride
Sponsor:	Pharmacia & Upjohn Co.
Approval Dates:	07/26/98; 08/18/98
Status:	Prescription only
Route:	Intramuscular, subcutaneous
Species:	Bovine (cattle including lactating dairy cattle)
Drug Form:	Liquid (suspension)
Concentration:	50 mg/mL ceftiofur
Indications:	For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella multocida*, *P. haemolytica*, and *Haemophilus somnus* and for the treatment of acute bovine interdigital necrobacillosis (foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.
Tolerance:	21CFR 556.113. An acceptable daily (ADI) for total residues is 30 micrograms/kilogram of body weight per day. A tolerance for the marker residue, desfuroylceftiofur, in the target tissue, kidney is 8 ppm, 2 ppm in liver, and 1 ppm in muscle. A tolerance of 100 ppb is established for residues of desfuroylceftiofur, the marker residue, in milk.
Withdrawal:	2 days
Patent Number:	4,902,683 Expiration Date: 02/20/2007
Exclusivity:	3 years

The supplemental application dated 7/26/98 provides for the use of an intramuscular or subcutaneous route of administration for Excenel® Sterile Suspension in new species cattle. The application dated 08/18/98 provides a revised label warning statement against use in veal calves.

21CFR 522.314 and *556.113*

NADA Number: 140-974

Trade Name:	Ivomec® Premix for Swine
Ingredients:	Ivermectin
Sponsor:	Merial Limited
Approval Date:	08/10/98
Status:	Over-the-counter
Route:	Oral
Species:	Porcine
Drug Form:	Type A medicated article to make Type B and C medicated feeds
Concentration:	0.6%
Indications:	For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and manage mites (*Sarcoptes scabiei* var *suis*), threadworms (*Strongyloides ransomi*, adults and somatic larvae), and the prevention of transmission of infective larvae to piglets via the colostrum or milk, when fed during gestation.
Tolerance:	21CFR 556.344: An Acceptable Daily Intake (ADI) for total residues of ivermectin is 1 microgram/kg of body weight per day. A tolerance of 20 ppb in liver (the target tissue) and muscle has been established for residues of 22, 23-dihydroavermectin $B_{1}a$ (the marker residue).
Withdrawal:	5 days
Exclusivity:	3 years

This supplemental application provides for a new claim for the treatment and control of threadworms and use of Type C medicated feed as a top-dressing for adult swine.

21CFR 558.300 and *556.344*

NADA Number: 048-761

Trade Name:	Aureomycin® Type A Medicated Article
Ingredients:	Chlortetracycline
Sponsor:	Roche Vitamins, Inc.
Approval Date:	07/31/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (chickens)
Drug Form:	Type A medicated article to make Type C medicated feeds
Concentration:	50, 90, and 100 grams/lb of chlortetracycline
	Indications: Chickens 10-50 g/ton: for increased rate of weight gain and improved feed efficiency in broiler/fryer chickens. 100-200 g/ton: for the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline. Feed continuously for 7 to 14 days. 200-400 g/ton: for the control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline. Feed continuously for 7 to 14 days. **Warning: Zero-day withdrawal period.** 500 g/ton: for the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline. Feed for 5 days. **Warning: Withdraw 24 hours prior to slaughter.**
Tolerance:	21 CFR 556.150: A tolerance is established for residues in eggs of 0.4 ppm. The ADI (Acceptable Daily Intake) for total residues (chlortetracycline, oxytetracycline, tetracycline) is 25 micrograms/kilogram of body weight per day.
Withdrawal:	Zero days
Exclusivity:	3 years

This supplemental application provides for use of a chlortetracycline Type A medicated article in Type C medicated feeds for chickens producing eggs for human consumption and a tolerance for residues in eggs.

21CFR 556.150, 556.500 and 556.720

Suitability Petition Action

Number:	98P-0862/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.
Action:	Filed on 10/01/98.

Number:	98P-0927/CP1
Sponsor:	Heska Corporation
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.
Action:	Filed on 10/21/98.

Number:	98P-0580/CP1
Sponsor:	Delmarva Laboratories, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe® Capsules, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristics: Clindamycin hydrochloride generic is a tablet and Antirobe® is a capsule.
Action:	Approved on 10/30/98

Patent and Trademark Office granted a second interim patent term extension for U. S. Patent # 4199569, owned by Merck & Company. The second interim extension was granted for an additional period of one year while a final determination of the regulatory review period for a human drug product, Stromectol®, was being made. The interim extension only applies to products that were approved after November 22, 1996, the date of approval of Stromectol®. The following information was provided by Merial Limited regarding the affected New Animal Drug Applications:

NADA Number	Trade Name	Patent Number	Expiration Date
128-409	Ivomec® Injection	4199569	10/3/1999*
128-409	Ivomec® Injection	4853372	08/1/2006
140-833	Ivomec® Plus	4199569	10/3/1999*
140-833	Ivomec® Plus	4853372	08/1/2006
140-841	Ivomec® Pour-On	4199569	10/3/1999*
141-078	Heartgard® for Cats	4199569	10/3/1999

*Applies only to the persistent activity claims for these products. Claims approved before 11/22/96 remain subject to the expiration date of 10/03/1997.